

AUG 18 2003

PTO-SB 08B (04-03)

Approved for use through 04/30/2003, OMB 0651-0031

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Page

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of

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Complete if Known

Application Number	09/423,100
Filing Date	December 11, 2000
First Named Inventor	Gan, Zhong-Ru
Art Unit	1647
Examiner Name	Nichols, Christopher J.
Attorney Docket Number	020167-000120US

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CONSIDERED; DO NOT PRINT.**U.S. PATENT DOCUMENTS**

Examiner	Cite No.	Document Number Number Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
CSJ	AA	US-5,422,110	06/06/1995	Potter et al.	
CSJ	AB	USSN 10/054,873	n/a	Gan	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)				
CSJ	AC	EP	0 645 454	A2	03/29/1995	Lunin et al.		
CSJ	AD	WO	96/23888	A1	08/08/1996	G.D. Searle & Co		
CSJ	AE	CA	1,341,211		03/27/2001	Hoechst Aktiengesellschaft		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
CSJ	AF	BIGGIO DATABASE: Accession number 100407207028. Samuelsson et al., 1994, "Enhanced <i>in vitro</i> refolding of insulin-like growth factor I using a solubilizing fusion partner," <i>Biochemistry</i> 33(14):4207-4211 (abstract)	
CSJ	AG	BIGGIO DATABASE: Accession number PRG/100700705120. Klappa et al., 1997, "Interactions between protein disulphide isomerase and peptides," <i>European Journal of Biochemistry</i> 248(1):37-42 (abstract)	

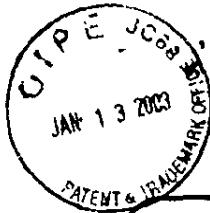
Examiner Signature	<i>Gan</i>	Date Considered	9/11/2003
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PTO SB 08A (10-01)

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Approved for use through 10/01/2018. GPO: 200-1000

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 3

Complete if Known

Application Number	09/423,100
Filing Date	December 11, 2000
First Named Inventor	Gan, Zhong-Ru
Art Unit	1647
Examiner Name	Saeud, Christine J. <i>JAN 14 2003</i>
Attorney Docket Number	020167-000120US

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U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner Signature	G. Nielson	Date Considered	3/6/2003
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[REDACTED] EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Kind Codes of U.S. Patent Documents at www.uspto.gov or MPEP 901.04 ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST 3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet

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Application Number	09/423,100
Filing Date	December 11, 2000
First Named Inventor	Gan, Zhong-Ru
Art Unit	1647
Examiner Name	Saeed, Christine J.

Attorney Docket Number

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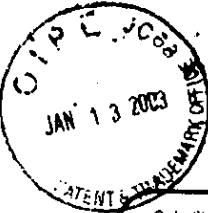
OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
CSJ	AG	U. Shinde and M. Inouye, "Intramolecular chaperones and protein folding," <i>TIBS</i> , (1993), Vol. 18, pp. 442-446.	—
CSJ	AH	M. Inouye, "Intramolecular Chaperone: The Role of the Pro-Peptide in Protein Folding," <i>Enzyme</i> , (1991), Vol. 45, pp. 314-321.	—
CSJ	AI	M. Ikehara, et al., "Synthesis of a gene for human growth hormone and its expression in <i>Escherichia coli</i> ," <i>Proc. Natl. Acad. Sci. USA</i> , (Oct. 1984), Vol. 81, pp. 5956-5960.	—
CSJ	AJ	Watson et al., <i>Recombinant DNA—A Short Course</i> , Scientific American Books, W.H. Freeman Co., NY, (1983), pp. 231-241.	—
CSJ	AK	Norman and Litwack, "Pancreatic Hormones: Insulin and Glucagon," in <i>Hormones</i> , Academic Press, Inc., NY, (1987), pp 264-317.	—
CSJ	AL	I. Johnson, "Human Insulin from Recombinant DNA Technology," <i>Science</i> , (Feb. 11, 1983), Vol. 219, pp. 632-637.	—
CSJ	AM	D. Williams, et al., "Cytoplasmic Inclusion Bodies in <i>Escherichia coli</i> Producing Biosynthetic Human Insulin Proteins," <i>Science</i> , (Feb. 5, 1982), Vol. 215, pp. 687-689.	—
CSJ	AN	R. Burgess, "Protein Purification," in <i>Protein Engineering</i> : Oxender, D.L., Fox, C.F., Eds.; Alan R. Liss, Inc; NY, (1987), pp. 71-82.	—
CSJ	AO	R.E. Chance, et al., "The Production of Human Insulin Using Recombinant DNA Technology and a New Chain Combination Procedure," in <i>Peptides: Synthesis-Structure-Function</i> , Pierce Chem. Co., Rockford, IL, (1981), pp. 721-728.	—
CSJ	AP	B.H. Frank and R.E. Chance, "The Preparation and characterization of human insulin of recombinant DNA origin," in <i>Therapeutic Agents Produced by Genetic Engineering "Quo Vadis?" Symposium</i> , (May 29-30, 1985), Sanoff Group, Toulouse-Labège, France, pp 137-148.	—
CSJ	AQ	R.E. Chance, et al., "Chemical, Physical, and Biological Properties of Recombinant Human Insulin," in J. L. Gueriguian <i>Insulins, Growth Hormone, and Recombinant DNA Technology</i> , Raven Press, NY, (1981), pp. 71-85.	—
CSJ	AR	R. D. Johnson, "The Processing of Biomacromolecules: A Challenge for the Eighties," <i>Fluid Phase Equilib.</i> , (1986), 29:109-123.	—
CSJ	AS	D. V. Goeddel, et al., "Expression in <i>Escherichia coli</i> of chemically synthesized genes for human insulin," <i>Proc. Natl. Acad. Sci. USA</i> , (Jan. 1979), No. 1, pp. 106-110.	—

Examiner Signature	<i>Saeed</i>	Date Considered	2/3/2003
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional) ²Applicant is to place a check mark here if English language Translation is attached

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 3

Complete if Known

Application Number	09/423,100
Filing Date	December 11, 2000
First Named Inventor	Gan, Zhong-Ru
Art Unit	1647
Examiner Name	Seoud, Christine J.

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Attorney Docket Number 020167-000120US

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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
CG	AT	J. P. Burnett, "Commercial Production of Recombinant DNA-Derived Products," in <i>Experimental Manipulation of Gene Expression</i> , Academic Press, NY, (1983), pp. 259-277.	
CG	AU	J. Etienne-Decent, "Regulation of Protein Synthesis," in <i>Genetic Biochemistry: From Gene to Protein</i> , Ellis Horwood Limited, Chichester, U.K., (1988), pp. 125-127.	
CG	AV	S. M. Wheelwright, <i>Protein Purification: Design and Scale up of Downstream Processing</i> , Oxford University Press, NY, (1991), p.217.	
CG	AW	B.H. Frank and R.E. Chance, "Two Routes for Producing Human Insulin Utilizing Recombinant DNA Technology," <i>Munch. Med. Wschr.</i> , (1983), Vol. 125, Suppl. 1, pp. S14-S20.	
CG	AX	E. P. Kroeff, et al, "Production Scale Purification of Biosynthetic Human Insulin by Reversed-Phase High-Performance Liquid Chromatography," <i>Journal of Chromatography</i> , (1989), Vol. 461, pp. 45-61.	
CG	AY	H. V. Tottrup and S. Carlsen, "A Process for the Production of Human Proinsulin in <i>Saccharomyces cerevisiae</i> ," <i>Biotechnol. Bieng.</i> , (1990), Vol. 35, pp. 339-348.	
CG	AZ	L. R. Castellanos-Serra, et al., "Expression and folding of an interleukin-2-proinsulin fusion protein and its conversion into insulin by a single step enzymatic removal of the C-peptide and the N-terminal fused sequence," <i>FEBS Letters</i> , (1996), Vol. 378, pp. 171-176.	
CG	BA	L. Villa-Komaroff, et al., "A bacterial clone synthesizing proinsulin," <i>Proc. Natl. Acad. Sci. USA</i> , (Aug. 1978), Vol. 75, No. 8, pp. 3727-3731.	
CG	BB	L. Thim, et al., "Secretion and processing of insulin precursors in yeast," <i>Proc. Natl. Acad. Sci. USA</i> , (Sept. 1986), Vol. 83, pp. 6766-6770.	
CG	BC	I. V. Diers et al., "Yeast Fermentation Processes for Insulin Production," in Y. H. Chiu <i>Drug Biotechnology Regulations: Scientific Basis and Practices</i> , Marcel Dekker, Inc., NY, (1991), pp. 166-176.	
CG	BD	M. R. Ladisch and K. L. Kohlmann, "Recombinant Human Insulin," <i>Biotechnol. Prog.</i> , (1992), Vol. 8, pp. 469-478.	

Examiner Signature

Date Considered

3/6/2003

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FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)			Attorney Docket No.: 20167-000120US		Application No.: 09/423,100	
			Applicant: Dr. Zhong-Ru Gan			
			Filing Date: October 29, 1999		Group: 1647	
Reference Designation		U.S. PATENT DOCUMENTS				
Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date (If Appropriate)
<i>CDAA</i>	6,001,604	12/14/99	Hartman et al.			
<i>CDAB</i>	4,916,212	04/10/90	Markussen et al.			
<i>CDAC</i>	4,342,832	08/03/82	Goeddel et al.			
<i>CDAD</i>	5,254,463	10/19/93	de Boer et al.			
FOREIGN PATENT DOCUMENTS						
	Document No.	Date	Country	Class	Sub-class	Translation (Yes/No)
<i>CDAE</i>	WO 96/20724	07/11/96	PCT			
<i>CDAF</i>	WO 97/18233	05/22/97	PCT			
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)						
EXAMINER	<i>G-Mutso</i>			DATE CONSIDERED	3/6/2003	

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